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In This Issue...

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Tamper-Resistant Prescription Pads

Important legislation was passed by Congress in May 2007 requiring prescriptions for all Medicaid outpatient drugs to be written on tamper-resistant prescription pads beginning October 1, 2007 in order to be eligible for federal reimbursement. This requirement was included in a provision in Section 7002(b) of the US Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007.

Tamper-resistant prescription pads contain security features specifically designed to prevent alterations and forgeries. The goal of this new law is to curtail illegal drug diversion caused by the forgery or theft of prescriptions. Because many of these drugs are resold to consumers, drug diversion is also a serious threat to public health.

In a CMS State Director's letter dated August 17, 2007, CMS offered guidance to State Medicaid agencies regarding the use of tamper-resistant prescription pads. The tamper-resistant prescription pad requirement becomes effective October 1, 2007 and applies to all outpatient drugs including over-the-counter drugs for which State Medicaid programs reimburse for prescriptions. Section 1927(k)(3) of the Social Security Act provides exceptions for drugs provided in nursing facilities, intermediate care facilities for the mentally retarded (ICF-MR), and other specified institutional and clinical settings such as those related to inpatient hospital, hospice, dental, physicians', laboratory, x-ray and renal dialysis services. Such drugs in these settings (to the extent that they are not separately reimbursed) are not subject to the tamper-resistant pad requirement. Section 7002(b) is applicable regardless of whether Medicaid is the primary or secondary payer of the prescription being dispensed. This law is applicable to dual eligibles who receive excluded medications from NC Medicaid. The law does not apply to prescription refills of prescriptions presented at a pharmacy before October 1, 2007. The law does not apply to e-prescriptions, faxed prescriptions, or prescriptions communicated to pharmacies by telephone by a prescriber. The law does not apply when a managed care entity pays for the prescription. This guidance does not restrict emergency fills of non-controlled or controlled substances for which a prescriber provides the pharmacy with a verbal, faxed, electronic, or compliant written prescription within 72 hours after the date on which the prescription was filled.

To be compliant with the tamper-resistant prescription pad requirements on **October 1, 2007**, a prescription pad must contain at least **one** of the following three characteristics:

1) one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form
2) one or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber
3) one or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

To be compliant with the tamper-resistant prescription pad requirements on **October 1, 2008**, a prescription pad **must** contain all **three** of the above characteristics.

This article provides North Carolina Division of Medical Assistance (DMA) guidance regarding the use of tamper-resistant prescription pads for prescriptions written for North Carolina Medicaid recipients. It is the responsibility of all North Carolina providers who write

prescriptions for NC Medicaid recipients to obtain from vendors, tamper resistant prescription pads which meet the characteristics noted above and are in compliance with Section 7002(b). DMA will not endorse specific vendors that supply tamper-resistant prescription pads.

A provider may choose one (1) of the following features for their prescription blanks in order to meet the October 1, 2007 requirement and at least one feature from each characteristic for a total of three (3) features to meet the October 1, 2008 requirement.

1. Industry-standard features that meet the requirements for characteristic #1:

a. A latent, repetitive "void" pattern or the word "void" appearing across the entire front of the prescription blank when photocopied or scanned.

b. A blue or green background ink on the prescription blank that resists reproduction.

c. The word "illegal" appearing across the entire front of the prescription blank when photocopied or scanned.

2. Industry-standard features that meet the requirements for characteristic #2:

a. A chemical void protection on the prescription blank that prevents alteration by chemical washing.

b The prescription blank may be made of quality safety paper that resists erasures and reproductions.

c. An area of opaque writing that disappears if the prescription blank is lightened.

d. Erasure protection on green or blue background on the front side of the prescription blank that resists alterations and erasures.

e. A feature printed in thermochromic ink that disappears or shows obvious tampering if the prescription blank is rubbed, scratched briskly, or if heat is applied.

f. Six quantity check off boxes printed on the prescription blank with the following quantities listed and may include a space to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form:

- 1-24
- 25-49
- 50-74
- 75-100
- 101-150
- 151 and over

3. Industry-standard features that meet the requirements for characteristic #3:

a. A description of security features included on each prescription blank.

b. A custom or repetitive watermark on the backside of the prescription blank that can be only seen at a forty-five (45) degree angle. The watermark should bear the name of the company manufacturing the prescription blank or should bear the word "security."

c. Logos, defined as a symbol utilized by an individual, professional practice, professional association or hospital, appearing on the prescription blank. The upper left one (1) inch square of the prescription blank should be reserved for the logo.

Pharmacists must continue to assure that prescriptions meet the requirements of 21 NCAC 46 .2301 which include the following:

1) date of issuance;

2) name and address of patient;

3) name, address and telephone number of prescriber except that indication of the name of the prescriber is sufficient if a data file specified in this rule is current and in effect;

4) Drug Enforcement Agency (DEA) number of prescriber in the case of controlled substances;

5) name, strength, dosage form and quantity of drug prescribed;

6) refills if authorized or, in institutions, the stop date;

7) route of administration of drug prescribed; and,

8) directions for use.

Pharmacists accepting prescriptions for NC Medicaid recipients are responsible for assuring that the prescriptions are compliant with the requirements of Section 7002(b). Pharmacists may accept out-of-state prescriptions that meet the requirements of Section 7002(b). **Prescriptions reimbursed by NC Medicaid on noncompliant prescription pads are subject to recoupment.**

Importance of One to One Enumeration

NC Medicaid strongly recommends that providers obtain an NPI for each Medicaid Provider Number in use today. Providers should mirror their Medicaid enrollment when enumerating. The only exception is for sole proprietors, who are only able to obtain one individual (Type I) NPI. When NPI is implemented, claims will continue to process through the current MMIS system. Therefore, NC Medicaid has designed a mapping solution to crosswalk the NPI to the Medicaid Provider Number used today. Ideally, each NPI will only crosswalk to one Medicaid Provider Number, otherwise known as a "one to one" match. If the NPI crosswalks to multiple Medicaid Provider Numbers, the NPI will have a "one to many" match. If a "one to many" match occurs, the mapping solution will attempt to determine the appropriate Medicaid Provider Number by taking the claim through a series of steps. Information such as Zip + 4 and taxonomy will play important roles in determining the appropriate Medicaid Provider Number.
If the mapping solution cannot narrow down to one Medicaid Provider Number, impacted claims may require additional research in order to process, and payment could be delayed.

To request additional NPIs, providers should complete an application by visiting the NPPES Web site: https://nppes.cms.hhs.gov. If you request additional NPIs, please be sure to report them to us as soon as possible. DMA forms and directions for reporting an NPI are located at http://www.dhhs.state.nc.us/dma/NPI.htm.

Emergency Supplies of Medications under Focused Risk Management

A NC Medicaid recipient who has opted in to a pharmacy is permitted up to a four-day emergency supply of medication for times when he or she is not able to get to the pharmacy to obtain medication. The pharmacy provider will be paid for the drug cost only, and the recipient will be responsible for the co-payment. A "3" in the Level of Service field (418-DI) indicates that the transaction is an emergency supply.

OxyContin Reimbursement

The Division of Medical Assistance is aware that generic versions of the medication OxyContin have limited availability. Since the federal upper limit (FUL) price will remain on the pharmacy drug file until the new average manufacturer's price (AMP)-based FULs are implemented, it is acceptable to dispense the brand name OxyContin and indicate DAW 1 on the claim transaction. This will override the FUL price and allow the claim to continue to process at the appropriate reimbursement rate.

Medication Therapy Management Is Now Focused Risk Management (FORM)

The program known as Medication Therapy Management (MTM) has been changed to Focused Risk Management (FORM) effective August 1, 2007. Details on this change are listed in the July 2007 Outpatient Pharmacy Program Special Bulletin, which is posted on DMA's Web site at www.ncdhhs.gov/dma.

The FORM process is initiated when the pharmacist tries to submit the 12th prescription at the point-of-sale (POS) during the claims adjudication process. A denial message will appear stating "maximum 11 prescriptions allowed per month." At this point, the pharmacist must call EDS to have the recipient opt-in to their pharmacy of choice. DMA has instructed EDS not to accept opt-ins from pharmacy providers prior to the recipient's 12th prescription.

The professional services fee that automatically paid on the first checkwrite of each month will no longer occur after the July payment (for June). Beginning in August, providers performing July FORM reviews for the third calendar quarter (July, August, and September) will need to document the date of service for the July review and submit the professional services fee at the POS as detailed in the July 2007 Outpatient Pharmacy Program Special Bulletin.

Field #	**Field Name**	**Required/ Optional/ Not Used**	**Field Type**	**Max Length**	**North Carolina Medicaid Specifications**
455-EM	Prescription/Service Reference Number Qualifier	Required	A/N	1	1=Prescription (Rx) Billing **2=Service Billing (e.g., Pharmacy management fee claims)**
477-BE	Professional Service Fee Submitted	Optional	N	8	Follow rules of the Implementation Guide ***Note this field is required for Pharmacy Management Fee claims**
426-DQ	Usual and Customary Charge	Required	N	8	Follow rules of the Implementation Guide
430-DU	Gross Amount Due	Required	N	8	Follow rules of the Implementation Guide

When submitting the professional services fee, the Professional Service Fee Submitted, Usual and Customary Charge, and Gross Amount Due fields must all be the same and no greater than the allowed quarterly fee of $30.00. If the fee claim is submitted with a value less than $30.00, it will be accepted. If a previously submitted claim for a fee needs to be corrected, the previous claim must be reversed prior to submitting the new claim.

Program Integrity Monitoring of Focused Risk Management Program

Program Integrity will perform audits to ensure adherence to the Focused Risk Management (FORM) policy. Details on this policy are listed in the July 2007 Outpatient Pharmacy Program Special Bulletin, which is posted on DMA's Web site at www.ncdhhs.gov/dma. Failure to perform the review as required by DMA policy, or failure to have documentation of the review on file at the time of audit, will result in the recoupment of the FORM fee payment as well as the payments for all claims that exceed the limit of 11 prescriptions per month. The signed documentation of the reviews must be kept on file in the pharmacy and readily retrievable for review by Program Integrity. If the primary care physician refuses to sign the FORM review, then the pharmacist must document the refusal on the review form. The name of the primary care physician who refused to sign and the reason for the refusal must be stated and dated. DMA will allow up to one month from the date of initial impartation to the primary care physician for the appropriate documentation for circumstances in which the physician refuses to sign the review form. Recoupment for not documenting quarterly reviews will not affect providers when recipients have opted in to their pharmacy for two months or less.

Addition to OTC Coverage List

The following Adeks OTC Products are now available for reimbursement by NC Medicaid in conjunction with a prescription order by the physician. The OTC list is located in the General Clinical Policy No. A-2 on the DMA Web site at http://www.dhhs.state.nc.us/dma/APA/A2.pdf.

Drug	NDC	Effective Date
Adeks Tab	58914-0010-06	9/12/2007
Aquadeks SoftGel	58914-0011-06	9/12/2007
Adeks Pediatric Drops	58914-0212-60	9/12/2007
Aquadeks Pediatric Liquid	58914-0214-60	9/12/2007

Changes in Drug Rebate Manufacturers

The following changes are being made in manufacturers with Drug Rebate Agreements. They are listed by manufacturer code, which are the first five digits of the NDC.

Additions

The following labelers have entered into Drug Rebate Agreements and have joined the rebate program effective on the dates indicated below:

Code	***Manufacturer***	***Date***
24338	Arbor Pharmaceuticals, Inc.	08/01/2007
66621	Rare Disease Therapeutics, Inc.	09/10/2007
67405	Harris Pharmaceutical, Inc.	09/06/2007
67857	Reddy Pharmaceuticals, Inc.	08/29/2007
68820	Northstar Rx, LLC.	09/06/2007

Voluntarily Terminated Labeler

The following labelers have requested voluntary termination effective January 1, 2008:

FEI Products LLC. (Labeler 50907)
Snuva Incorporated. (Labeler 58291)

Checkwrite Schedule

September 11, 2007	October 09, 2007	November 06, 2007
September 18, 2007	October 16, 2007	November 14, 2007
September 27, 2007	October 23, 2007	November 21, 2007
	October 31, 2007	

Electronic Cut-Off Schedule

September 06, 2007	October 04, 2007	November 01, 2007
September 13, 2007	October 11, 2007	November 08, 2007
September 20, 2007	October 18, 2007	November 15, 2007
	October 25, 2007	November 29, 2007

Electronic claims must be transmitted and completed by 5:00 p.m. on the cut-off date to be included in the next checkwrite. Any claims transmitted after 5:00 p.m. will be processed on the second checkwrite following the transmission date. POS claims must be transmitted and completed by 12:00 midnight on the day prior to the electronic cut-off date to be included in the next checkwrite.

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